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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/019,048

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Ernst Heinz

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/019,048	Applicant(s) HEINZ ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Election/Restriction

Claims 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/10/03.

Priority

The translation of the German Priority (DE 100 30 976.2) document is not sufficient to perfect the foreign priority filing date because the translated copy was not filed together with a statement that the translation of the certified copy is accurate (See 37 CFR 1.55(a)(3) and MPEP 706.02(b). A translation of the PCT/EP00/06223 application is also acknowledged; however, an English translation of the PCT document is already of record.

Priority for the claimed invention is granted back to the filing date of the PCT/EP00/06223 application, filed 7104/2000. Support for the instant claims is not found in the US 09/347,531 (hereafter the '531 application) application and until a suitable English translation (accompanied by a statement that the translation of the certified copy is accurate) of the German application 100 30 976.3 is provided, priority cannot be granted back to the filing date of the German document.

Applicants assert that the instantly claimed homology ranges are supported by the disclosure of the 09/347,531 application (hereafter the '531 application) and that the

'531 application provides support for the limitation of at least 1 mol% unsaturated fatty acid based upon the total fatty acid content.

Applicant's arguments filed 2/19/08 have been fully considered but they are not fully persuasive. Initially, it is noted that applicants' arguments with regard to the claimed homology ranges are persuasive. However, when the full scope of the instant claims is examined, it is clear that the '531 application does not support the full scope of the claimed subject matter. For example, while the '531 application may strictly support the instantly claimed homology limitations, it does not support the limitation of nucleic acids encoding the polypeptide with the amino acid sequence shown in SEQ ID NO: 2 or a polypeptide having at least 95% (or 85%) homology at the amino acid level **without substantially reducing the Δ 6-desaturase activity of the polypeptide**. Also, the '531 application does not support the claimed process of preparing unsaturated fatty acids comprising introducing **into any organism**, the recited nucleic acid molecules and culturing said organism to contain at least 1 mol% unsaturated fatty acid based upon the total fatty acid content. The '531 application provides support for introducing the recited nucleic acid into a yeast cell to generate the recited unsaturated fatty acids and the application contemplates preparing transgenic plants with the recited nucleic acids, but provides no broader teachings on any other organisms. No support is provided in the '531 application for the instant claims reading on performing the recited process in alga, ciliates, cyanobacteria, etc.

The '531 application provides no support for the limitation of a process for preparing an unsaturated fatty acid in any organism, culturing said organism, wherein

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the cultured organism contains **at least 1 mol% of unsaturated fatty acid based on the total fatty acid content in the organism**. This limitation has no upper limit and reads on 1 mol% to 100 mol% of unsaturated fatty acid based on the total fatty acid content in the organism. Applicants argue that p. 6, lines 25-40 of the '531 application provides support for this limitation. However, an examination of this portion of the '531 application provides no support for the limitation of organisms containing "at least 1 mol% unsaturated fatty acid based upon the total fatty acid content". The recited portion of the '531 application is a Table showing the Total Fatty Acids (%) obtained in a single yeast strain comprising the recited nucleic acid encoding the *Physcomitrella patens* gene encoding $\Delta 6$ -desaturase.

The '531 application provides no support for transgenic organisms selected from the group consisting of a plant, a fungus, a ciliate, an alga, a bacterium, and a cyanobacterium comprising at least one isolated nucleic acid sequence encoding a polypeptide with $\Delta 6$ -desaturase activity, selected from the group consisting of:

- a) a nucleic acid sequence having the sequence shown in SEQ ID NO: 1,
- b) a nucleic acid sequence which, as a result of the degeneracy of the genetic code, is derived from the sequence shown in SEQ ID NO: 1,
- and c) a derivative of the nucleic acid sequence shown in SEQ ID NO: 1 which encodes the polypeptide with the amino acid sequence shown in SEQ ID NO: 2 or a polypeptide having at least 85% homology at the amino acid level without substantially reducing the $\Delta 6$ -desaturase activity of the polypeptide. The application only provides

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support for a transgenic yeast and contemplates generating transgenic plants comprising the recited nucleic acid sequences.

The '531 application provides no support for the limitations of instant claims 14 and 15 wherein homology ranges are recited and the **encoded polypeptides have not less than 30% or 100% of the enzymatic activity of SEQ ID NO:2.**

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 13-14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Girke et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. **It is noted that the examiner, in the previous Office Action, incorrectly indicated that the rejection was applied under 35 USC 102(a) rather than 102(b).** Since applicants' invention is granted priority back to the filing date of the PCT/EP00/06223 application (filed 7/4/2000), the publication date of the Girke et al. reference (7/28/1998) **is more than ONE year prior to applicants' effective filing date** and is therefore a 102(b) reference.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girke et al. in view of Napier et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants have responded to these rejections by submitting a 37 CFR 1.131 Declaration attempting to swear behind the Girke et al. reference. The evidence presented by applicants is a copy of a portion of the Doctoral Thesis of Thomas Girke.

The 1.131 Declaration filed on 2/19/08 under 37 CFR 1.131 has been considered but is ineffective to overcome the 35 USC 102(b) reference. Initially, it is noted that a 37 CFR 1.131 Declaration cannot be used to overcome a reference applied under 35 USC

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102(b). Second, even if the outstanding rejection were under 35 USC 102(a) rather than 102(b), the scope of the evidence presented in the Doctoral thesis is not commensurate with the scope of the claimed invention. For example, the instant claims read not only on SEQ ID NO:1 and 2 but also on a genus of nucleic acid molecules derived from SEQ ID NO:1 wherein said molecules encode polypeptides having at least 95% (or 85%) homology at the amino acid level with SEQ ID NO:2 without having substantially reduced $\Delta 6$ -desaturase activity and use of said sequences to prepare an unsaturated fatty acid in any organism wherein the organism contains at least 1 mol% of unsaturated fatty acid based upon the total fatty acid content in the organism. The evidence presented in the Thesis involves expression of SEQ ID NO:1 in yeast cells. No disclosure is provided concerning expression of any of the genus of nucleic acids encompassed within the instant claims in any other organism so as to achieve the claimed mol% of fatty acids. No disclosure is provided of any transgenic organisms other than the specific yeast cells transformed with SEQ ID NO:1. No disclosure is provided in the Thesis concerning other derivatives of SEQ ID NO:1 which are at least 90% homologous to SEQ ID NO:1 and have not less than 30% or 100% of the enzymatic activity of SEQ ID NO:2. Since the evidence presented in the 1.131 Declaration is insufficient to show that applicants were in possession of the claimed subject matter, said Declaration is insufficient to overcome the outstanding 35 USC 102(b) rejection.

35 USC 112, 1st Paragraph Rejections

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for expressing the recited A6-desaturases (i.e. a nucleic acid sequence having the sequence shown in SEQ ID NO: 1, nucleic acid sequences which, as a result of the degeneracy of the genetic code, are derived from the sequence shown in SEQ ID NO:1, and a derivative of the nucleic acid sequence shown in SEQ ID NO: 1 which encode polypeptides with the amino acid sequence shown in SEQ ID NO: 2 and has at least 95% homology at the amino acid level without substantially reducing the A6-desaturase enzymatic activity of the polypeptides) in plants, alga, fungi or bacteria, does not reasonably provide enablement for expression of the recited A6-desaturases in animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is re-instated for and applied for reasons of record in the Office Actions mailed 10/7/05 and 6/1/07. It is noted that applicants' amendment of claim 4 to recite "animal cells" in the amendment filed 7/31/07 was sufficient to overcome the rejection against claim 4; however, claims 1-3 and 7-8 were not amended and still read on expression in animals. The examiner however inappropriately withdrew the rejection against claims 1-3 and 7-8 in the Office Action of 11/16/07. The rejection is hereby re-instated.

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No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 4, 2008

/David Guzo/
Primary Examiner
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